Semmelweis University, Faculty of Medicine

Pharmaceutical Innovation and Business Adminstration Master of Science

Name of the host institution (and any contributing institution):

Department of Pharmacology and Pharmacotherapy hosting the MSc course announcing this specific subject in collaboration with the Centre for Translational Medicine

Name of subject: Critical literature reading

in English: Critical literature reading

in German: not applicable

Credit value: 5

Semester: 2025/2026 1st Semester

in which the subject is taught according to the curriculum

Hours per semester	Lecture	Course work	Seminar
150	25	125	

Hours per week	Lecture	Course work	Seminar
Course blocks tailored to the students' employment obligations. Course dates: 10 Oct 14.00-18.00 6 Nov 08:00-16:00 28 Nov 14.00-18.00			

Type of course:

compulsory

Academic year:

2025/2026

Language of instruction (for optional and elective subjects):

English

Course code: new course

(in the case of a new course, to be completed by the Dean's Office, following approval

Course coordinator name: Prof. Dr. Péter Hegyi

Course coordinator location of work, telephone availability: Semmelweis University, Centre for Translational Medicine, +36-30/0164407

Course coordinator position: Professor

Course coordinator Date and number of habilitation: 2011

Objective of instruction and its place in the curriculum: The objective of instruction is to develop students' ability to critically assess scientific publications and engage with current research in a structured and analytical manner. The course lays a foundation for evidence-based thinking and supports the development of research competencies essential for advanced academic work and thesis preparation.

Method of instruction (lecture, group work, practical lesson, etc.):

Lectures, group work, home-works, and e-learning.

Competencies acquired through completion of course: Through completion of the course, students will acquire the ability to critically evaluate scientific literature, interpret research findings, and identify strengths and limitations in published work. They will also develop skills in evidence-based reasoning, academic collaboration, and independent learning.

Course outcome (names and codes of related subjects):

none

Prerequisites for course registration and completion: (CODE):

none

In the case of multi-semester courses, position on the possibility of and conditions for concurrent registration:

none

The number of students required to start the course (minimum, maximum), student selection method:

all students admitted

Detailed course syllabus (if the course can be divided into modules, please indicate):

(Theoretical and practical instruction must be broken down into hours (weeks), numbered separately; names of instructors and lecturers must be listed, indicating guest lecturers/instructors. It cannot be attached separately! For guest lecturers, attachment of CV is required in all cases!)

Course topics include:

Introduction to evidence-based research and the role of systematic reviews

Formulating research questions using the PICO framework

Literature search strategies and database use (e.g., PubMed, Cochrane Library)

Study selection, inclusion/exclusion criteria, and data extraction

Assessing the quality and risk of bias in individual studies

Introduction to meta-analysis: concepts, effect measures, and heterogeneity

Strengths and limitations of systematic reviews and meta-analyses

Common sources of bias and how to identify them

Reporting standards (e.g., PRISMA) and transparency in methodology

Critical appraisal of published systematic reviews and meta-analyses

Course structure:

Lectures: Theoretical background on methodology and key concepts

E-learning: Online video modules to support self-paced learning

Practical sessions: Group and individual work focused on real-world examples

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Other courses with overlapping topics (obligatory, optional, or elective courses) in interdisciplinary areas. To minimalize overlaps, topics should be coordinated. Code(s) of courses (to be provided): None

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Requirements for attendance, options for making up missed sessions, and method of absence justification: Full attendance is required. Completing additional e-learning materials are required to make up missed courses.

Assessment methods during semester (number, topics, and dates of midterms and reports, method of inclusion in the course grade, opportunities for make-up and improvement of marks):

(number, topics, and dates of midterms and reports, method of inclusion in the course grade, opportunities for make-up and improvement of marks)

Attendance, group work activity.

Number and type of individual assignments to be completed, submission deadlines: January 26, 2026

Requirements for the successful completion of the course: Attendance and passed project work.

Type of assessment:

Project work

Examination requirements (list of examination topics, subject areas of tests, lists of mandatory parameters, figures, concepts and calculations, practical skills, optional topics for the project assignment recognized as an exam and the criteria for its completion and evaluation)

All materials will be provided during the course

Method and type of grading (Share of theoretical and practical examinations in the overall evaluation. Inclusion of the results in the end-of-term assessment. Possibilities of and conditions for offered grades.): (Share of theoretical and practical examinations in the overall evaluation, Inclusion of the results in the end-of-term assessment, Possibilities of and conditions for offered grades)

Passed/ Failed – practical exam based on the project work

Signature of habilitated instructor (course coordinator) announcing the course:

Prof. Dr. Péter Hegyi

Signature of the director of the host institution:

Prof. Dr. Péter Hegyi

Date of submission:

8th August 2025

Semmelweis University, Faculty of Medicine

Pharmaceutical Innovation and Business Administration Master of Science

Name of the host institution (and any contributing institution):

Department of Pharmacology and Pharmacotherapy in collaboration with the Institute of Biostatistics and Network Science of Semmelweis University

Name of subject:

Data management and statistics

in English: Data management and statistics

in German: Not applicable

Credit value: 5

Semester: 2025/2026 1st Semester

in which the subject is taught according to the curriculum

Hours per semester	Lecture	Course work	Consultation
150	15	130	5

Hours per week	Lecture	Course work	Consultation
Course blocks tailored to the students' employment obligations on Fridays and Saturdays Course dates: 4th October 9.00-12.00 17th October 9.00-12.00 24th October 14.00-18.00 7th November 14.00-18.00 13rd December 9.00-12.00			

Type of course:

compulsory

Academic year:

2025/2026

Language of instruction (for optional and elective subjects):

English

Course code:

(in the case of a new course, to be completed by the Dean's Office, following approval

Course coordinator name: Dr. Roland Molontay

Course coordinator location of work, telephone availability: Semmelweis University, 1082 Budapest, Baross u. 22 tel.: +36205913228

Course coordinator position: Director

Course coordinator Date and number of habilitation:

Objective of instruction and its place in the curriculum:

The aim of the course is to equip students with the skills to recognize business and operational challenges within the pharmaceutical and healthcare sectors where data analysis and data science can provide strategic value. Through practical prototyping, students will learn to demonstrate and communicate the competitive advantages of data-driven solutions. The course covers both theoretical and practical foundations of data analysis methods relevant to economic and managerial decision-making in the life sciences industry. Students will acquire quantitative tools for analyzing and predicting industry-relevant phenomena. Beyond delivering essential theoretical knowledge, the course emphasizes practical problem-solving, real-world case studies, and the cultivation of a data-oriented mindset tailored to the pharmaceutical business environment.

Method of instruction (lecture, group work, practical lesson, etc.): real-time online lectures

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Competencies acquired through completion of course:

1. Understands the key tasks of business data analysis, the main areas of expertise, and the tools applicable in each.
2. Understands the technical details of the main steps in data analysis: data collection, data preparation, modeling, evaluation, and application.
3. Has knowledge of the most important theoretical models and algorithms in data science, including the basic paradigms of supervised and unsupervised machine learning.
4. Knows the fundamental tools and methods of data visualization.
5. Is familiar with the basic operation of data-driven decision support tools.
6. Understands the most important micro- and macroeconomic applications of data science, data analysis, and data visualization, particularly in the field of business intelligence.
7. Is aware of the learning, knowledge acquisition, and data collection methods used in data analysis, as well as their ethical limitations and problem-solving techniques.
8. Can identify business problems to which data science or machine learning solutions can be applied.
9. Can prototype possible solutions, visualize results, and identify business value to inform decision-making and guide further analysis.
10. Can apply learned theories and methods to explore, systematize, and analyze facts and relationships; formulate independent conclusions and critical observations; propose and evaluate decisions in both routine and partially unknown domestic and international contexts.
11. Are able to determine the complex consequences of economic processes and organizational events.

12. Can apply data analysis problem solving techniques, problem solving methods, their application conditions and limitations.
13.
14. Collaborate effectively with instructors and peers to expand collective knowledge.
15. Continuously develops expertise through independent and ongoing learning.
16. Demonstrates openness to and proficiency in using information technology tools.
17. Shows problem sensitivity, proactive behavior, and constructive cooperation in projects and group tasks to ensure high-quality outcomes.
18. Strives for accuracy and error-free problem solving.
19. Works independently with responsibility, including the selection of appropriate methodologies and techniques, as well as the organization, planning, and management of tasks.
20. Collects, systematizes, analyzes, and evaluates data effectively while fostering both general and professional growth.
21. Applies a systems-oriented approach to thinking and problem solving.
22. Takes full responsibility for analyses, conclusions, and decisions.

Course outcome (names and codes of related subjects):

none

Prerequisites for course registration and completion: (CODE): -

none

In the case of multi-semester courses, position on the possibility of and conditions for concurrent registration:

none

The number of students required to start the course (minimum, maximum), student selection method:

all students admitted

Detailed course syllabus (if the course can be divided into modules, please indicate):

(Theoretical and practical instruction must be broken down into hours (weeks), numbered separately; names of instructors and lecturers must be listed, indicating guest lecturers/instructors. It cannot be attached separately! For guest lecturers, attachment of CV is required in all cases!)

Each lecture - 45 minutes

Lecture 1:

- Introduction to Data Science – History, key concepts, objectives
- Overview of job roles, tools, and fields of application (with examples from pharmaceutical and business contexts)

Lecture 2:

- Data Discovery – Identifying and sourcing relevant datasets

- Examples from pharmaceutical innovation, healthcare, and market analysis

Lecture 3:

- Data Preparation – Cleaning, transforming, and organizing data
- Practical exercise with a sample dataset

Lecture 4:

- Data Visualization I – Principles of effective visual communication
- Introduction to visualization tools (e.g., Tableau, Power BI, Python libraries)

Lecture 5:

- Data Visualization I (continued) – Basic chart types, best practices, and common pitfalls
- Hands-on: Creating clear and informative visuals

Lecture 6:

- Supervised Machine Learning I – Concept of supervised learning
- k-Nearest Neighbors (kNN): Theory and example applications

Lecture 7:

- Supervised Machine Learning I (continued) – Decision Trees: concept, strengths, and limitations
- Short practical demo with sample data

Lecture 8:

- Supervised Machine Learning II – Introduction to ensemble methods (bagging, boosting, random forests)

Lecture 9:

- Supervised Machine Learning II (continued) – Neural Networks: basic architecture and applications in pharma/business

Lecture 10:

- Model Evaluation and Validation – Performance metrics (accuracy, precision, recall, F1-score)

Lecture 11:

- Model Evaluation and Validation (continued) – Cross-validation, train/test splits, avoiding overfitting
- Short lab exercise to compare models

Lecture 12:

- Unsupervised Machine Learning – Concept and applications
- k-Means clustering: theory and process

Lecture 13:

- Unsupervised Machine Learning (continued) – Practical example with clustering in a business or pharma dataset

Lecture 14:

- Integrated Case Study – From data discovery to visualization and modelling
- Applying both supervised and unsupervised methods in a real-world scenario

Lecture 15:

- Review and Discussion – Key takeaways, open Q&A, industry applications
- Guidance for further study and project work

Other courses with overlapping topics (obligatory, optional, or elective courses) in interdisciplinary areas. To minimalize overlaps, topics should be coordinated. Code(s) of courses (to be provided): -

none

Requirements for attendance, options for making up missed sessions, and method of absence justification:

Full attendance is required. Completing additional e-learning materials are required to make up missed courses.

Assessment methods during semester (number, topics, and dates of midterms and reports, method of inclusion in the course grade, opportunities for make-up and improvement of marks):

test and project work submitted at the end of the semester

Number and type of individual assignments to be completed, submission deadlines: -

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Requirements for the successful completion of the course: successful completion of the test at the end of the semester (>50%)

Type of assessment: test

Examination requirements (list of examination topics, subject areas of tests, lists of mandatory parameters, figures, concepts and calculations, practical skills, optional topics for the project assignment recognized as an exam and the criteria for its completion and evaluation)

same as course syllabus

Method and type of grading (Share of theoretical and practical examinations in the overall evaluation. Inclusion of the results in the end-of-term assessment. Possibilities of and conditions for offered grades.):

Written end-term test: during the semester, the course material will be tested with a written end-term test. The test consists of theoretical questions and calculations. At least 50% of the points of the mid-term test must be obtained in order to obtain the signature and pass the course.

test: 70% theoretical, 30% practical

Grading Scale

- Excellent: 90–100
- Good: 80–89
- Satisfactory: 65–79
- Pass: 50–64
- Fail: <50

Signature of habilitated instructor (course coordinator) announcing the course:

Prof. Dr. Péter Ferdinandy	Dr. Roland Molontay
Head of Department	Director

Signature of the director of the host institution:

Prof. Dr. Péter Ferdinandy
Head of Department

Date of submission:

11th August 2025

Semmelweis University, Faculty of Medicine

Pharmaceutical Innovation and Business Administration Master of Science

Name of the host institution (and any contributing institution):

Department of Pharmacology and Pharmacotherapy under the umbrella of the Centre for Pharmacology and Drug Research & Development, in collaboration with the Department of Pharmaceutics at Faculty of Pharmaceutical Sciences

Name of subject:

Authorization and approval of medicinal products

in English: Authorization and approval of medicinal products

in German: not applicable

Credit value: 5

Semester: 2025/2026 1st

in which the subject is taught according to the curriculum

Hours per semester	Lecture	Course work	Consultation
150	14	125+8 hours project work presentation	3

Hours per week	Lecture	Course work	Consultation
Course blocks tailored to the students' employment obligations on Fridays and Saturdays Course dates: 3rd October 14.00-18.00 15th November 9.00-12.00 22nd November 9.00-12.00 12th December 14.00-18.00 Project work presentations 24th January			

Type of course:

compulsory

Academic year:

2025/2026

Language of instruction (for optional and elective subjects):

English

Course code:

(in the case of a new course, to be completed by the Dean's Office, following approval

Course coordinator name: Prof. Istvan Antal

Course coordinator location of work, telephone availability:
Department of Pharmaceutics, +36206632740

Course coordinator position: professor, director

Course coordinator Date and number of habilitation: 2003, 8/2003 SZTE

Objective of instruction and its place in the curriculum:

The objective of the course is to review the authorization process of medicinal products as well as the aspects of the development and evaluation of the information and documentation required for approval. Students will learn the basics of marketing authorization, the regulatory environment and system of requirements that determine the content and formal requirements of technical documentation, including drug quality, as well as the tasks related to the application for marketing authorizations, official evaluation and the maintenance of authorizations. The subject provides an overview of industrial and official processes prior to placing on the market. It presents, in general, the activities and knowledge materials required for maintaining and amending the license after obtaining it.

Method of instruction (lecture, group work, practical lesson, etc.):

lectures, project work.

Competencies acquired through completion of course:

Completing the course the students should be able to use knowledge about the regulatory requirements including documentation and approval of medicinal products.
Students acquire several competencies including:

- understanding the approval process and requirements for development, registration.
- understanding the significance of quality, safety, efficacy and their relationship and aspects related to authorization,
- knowledge of regulatory directives and guidelines (e.g. ICH, EMA, FDA)
- knowledge of requirements for the structure and submission of documentation (Common Technical Document, CTD).
- knowledge of structure and content of Product Information documents (Summary of Product Characteristics (SmPC) and Patient Information Leaflets (PIL), package inserts

Course outcome (names and codes of related subjects):

The course will serve as a basis for general aspects of phamaceutical innovations and product development. Related subjects are: Food supplements: development, market and regulation, Manufacturing- Pharmaceutical formulation, optimization, quality assurance, logistics, supply chain

Prerequisites for course registration and completion: (CODE):

none

In the case of multi-semester courses, position on the possibility of and conditions for concurrent registration:

none

The number of students required to start the course (minimum, maximum), student selection method:

all students admitted to the MSc course

Detailed course syllabus (if the course can be divided into modules, please indicate):

(Theoretical and practical instruction must be broken down into hours (weeks), numbered separately; names of instructors and lecturers must be listed, indicating guest lecturers/instructors. It cannot be attached separately! For guest lecturers, attachment of CV is required in all cases!)

- Introduction: aspects of quality, safety and efficacy
  How medicinal products are approved. Evolution of drug authorization and approval
- From laboratory to the patient: research and developments, scientific advices, evaluation, authorization, access, monitoring safety
- Roles and responsibilities Data integrity requirements
- Drug authorization procedures, types of the marketing authorisation.
  Modification processes of already authorized pharmaceutical products
- Legal framework, regulatory directives and guidelines (e.g. ICH, EMA, FDA)
- Marketing authorisation of a new medicinal product assessed by a professional authority
- Registration documentation.
  Structure and submission of documentation (Common Technical Document, CTD).
  Product Information documents (Summary of Product Characteristics (SmPC) and Patient Information Leaflets (PIL), package inserts
- The planning process for the development of original medicines
  The planning process for the development of generic drugs
- Planning process for the development of generic added value medicines
  Biological medicines and biosimilar preparations
  Planning of WEU and its traditional development
- Aspects of pharmacovigilance, clinical trials
- Aspects of quality assurance
- Audits and inspections in pharmaceutical production

Other courses with overlapping topics (obligatory, optional, or elective courses) in interdisciplinary areas. To minimalize overlaps, topics should be coordinated. Code(s) of courses (to be provided):

Food supplements: development, market and regulation, Manufacturing- Pharmaceutical formulation, optimization, quality assurance, logistics, supply chain

Requirements for attendance, options for making up missed sessions, and method of absence justification:

Full attendance is required. Consultations are required to make up missed courses.

Assessment methods during semester (number, topics, and dates of midterms and reports, method of inclusion in the course grade, opportunities for make-up and improvement of marks):

(number, topics, and dates of midterms and reports, method of inclusion in the course grade, opportunities for make-up and improvement of marks)

Students can improve the marks according to the general regulations

Number and type of individual assignments to be completed, submission deadlines:

Personal attendance of lectures and practical expected according to study regulations. The written test (last educational week) must be passed ("accepted").

Completed individual work can be selected from several topics of approval procedures, e.g. related to

- Common Technical Documentation

- Summary of product characteristics (SmPC), patient information,

- Quality aspects

Requirements for the successful completion of the course:

Attendance of lectures, preparation and interpretation of project works, written test

Type of assessment:

written test and oral (presentation of project work)

Examination requirements (list of examination topics, subject areas of tests, lists of mandatory parameters, figures, concepts and calculations, practical skills, optional topics for the project assignment recognized as an exam and the criteria for its completion and evaluation)

Lecture slides will be published on Moodle with test questions related to reviewed topics.

Method and type of grading (Share of theoretical and practical examinations in the overall evaluation. Inclusion of the results in the end-of-term assessment. Possibilities of and conditions for offered grades.): (Share of theoretical and practical examinations in the overall evaluation, Inclusion of the results in the end-of-term assessment, Possibilities of and conditions for offered grades)

Formulation of the grade:
88 to 100 points: excellent (5)
76-87,5 points: good (4)

63-75 points: average (3)
50-62 points: satisfactory (2)
Less than 50 points: unsatisfactory (1)

Half of the points are coming from the test, half from the assessment of the project work.

Signature of habilitated instructor (course coordinator) announcing the course:

Prof. Dr. István Antal

Dean

Signature of the director of the host institution:

Prof. Dr. Péter Ferdinandy	Prof. Dr. István Antal
Head of Department	Dean

Date of submission:

11th August 2025

Semmelweis University, Faculty of Medicine

Pharmaceutical Innovation and Business Administration Master of Science

Name of the host institution (and any contributing institution):

Department of Pharmacology and Pharmacotherapy

Name of subject: Fundamentals in Pharmacology

in English: Fundamentals in Pharmacology

in German: not applicable

Credit value: 5

Semester: 2025/2026 1st Semester

Hours per semester	Lecture	Course work	Seminar
150	17	116	9

Hours per week	Lecture	Practical lesson	Seminar
Course blocks tailored to the students' employment obligations on Fridays and Saturdays Course dates: 14th November 14.00-18.15 29th November 9.00-13.00 5th December 14.00-18.00 6th December 9.00-13.00 seminar 23rd January 9.00-17.00			

Type of course:

compulsory

Academic year:

2025/2026

Language of instruction (for optional and elective subjects):

English

Course code:

(in the case of a new course, to be completed by the Dean's Office, following approval

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Course coordinator name: Prof. Dr. Peter Ferdinandy

Course coordinator location of work, telephone availability: Department of Pharmacology and Pharmacotherapy, 1089 Budapest, Nagyvárad tér 4. Tel: +36-1-2104416, e-mail: ferdinandy.peter@semmelweis.hu

Course coordinator position: Head of Department, full professor

Course coordinator Date and number of habilitation: June 2 2001., 26/2001 Hab.

Objective of instruction and its place in the curriculum:

During the first part of the *Fundamentals in Pharmacology* course, students are introduced to the principles of assigning drugs to specific disorders based on pharmacotherapeutic protocols. Emphasis is placed on problem-oriented thinking to develop therapeutic strategies for priority public health conditions, in accordance with current clinical guidelines. This foundational knowledge is delivered through a combination of pre-recorded video lectures, handouts, and consultation sessions.

In the second part of the semester, the course shifts its focus to current trends in pharmacotherapy development. Key therapeutic areas—such as cardiology, oncology, neurodegenerative disorders, and immunology—are explored in depth. Additionally, cross-cutting themes including personalized medicine, advanced therapy medicinal products (ATMPs), vaccine development, and RNA-based therapies are also addressed.

Method of instruction (lecture, group work, practical lesson, etc.):

pre-recorded online lectures

real-time online lectures

in-person seminar

Competencies acquired through completion of course:

- awareness of major diseases of public health importance
- foundational pharmacological knowledge
- a pharmacotherapeutic strategy for diseases of public health importance according to current guidelines
- insight into ongoing developments in major therapeutic areas (e.g., cardiology, oncology).
- understanding of advanced therapy medicinal products (ATMPs), personalized medicine, RNA therapies, and vaccine development.
- ability to discuss and evaluate emerging drug technologies and their implications for future practice.
- skills in utilizing various learning resources (videos, handouts, consultations) effectively.

- encouragement of self-directed learning and staying updated with evolving medical knowledge.

Course outcome (names and codes of related subjects):

none

Prerequisites for course registration and completion: (CODE):

none

In the case of multi-semester courses, position on the possibility of and conditions for concurrent registration:

none

The number of students required to start the course (minimum, maximum), student selection method:

all students admitted

Detailed course syllabus (if the course can be divided into modules, please indicate):

(Theoretical and practical instruction must be broken down into hours (weeks), numbered separately; names of instructors and lecturers must be listed, indicating guest lecturers/instructors. It cannot be attached separately! For guest lecturers, attachment of CV is required in all cases!)

Modul I – Basic clinical pharmacology

1. Infectious Diseases Treatment Strategy - Dr. Kornél Király, associate professor; Dr. Zsófia Gulyás-Onódi, assistant professor; Dr. Erzsébet Kató, assistant professor – 2 hours

2. Treatment strategy for respiratory and gastrointestinal diseases - Dr. Klára Gyires, Professor Emerita, clinical pharmacologist, Dr. Zoltán Zádori, associate professor - – 2 hours

3. Endocrine Disease Treatment Strategy - Dr. Bence Ágg, associate professor, Dr. Júlia Timár, retired associate professor - – 2 hours

4. Treatment strategy for cardiovascular diseases and metabolic syndrome - Dr. Péter Ferdinandy, professor, clinical pharmacologist, Dr. Anikó Görbe, professor, specialist in clinical laboratory tests, specialist in psychotherapy, Dr. Zoltán Varga, associate professor - – 2 hours

5. Strategy for the treatment of psychiatric and neurological diseases - Dr. István Gyertyán, Research associate, Dr. László Hársing, retired professor, Dr. Ildikó Miklya, retired associate professor – 2 hours

6. Pain Relief - Dr. Al-Khrasani Mahmoud, associate professor, pharmacist in drug supply and organization, Dr. Kornél Király, associate professor – 2 hours

7. Treatment strategy of autoimmune diseases - Dr. Klára Gyires, professor emeritus, specialist in clinical pharmacology, Dr. Zoltán Zádori, associate professor – 2 hours

8. Individualized pharmacotherapy, special patient populations - Dr. Zsófia Gulyás-Onódi, assistant professor, Dr. Ildikó Miklya, retired associate professor – 2 hours

Modul II – trends in the development of pharmacotherapies

9. Development and clinical application in advanced therapy medicinal products (ATMPs) – Dr. Tamás Masszi, professor, László Cervenák PhD – 2 hours

10. Current trends in neuropsychiatric pharmacology – Prof. Dr. István Bitter, professor – 2 hours

11. Exploring the promise of RNA-based therapies: Current Advances and Future Prospects – Prof. Dr. Péter Ferdinandy, professor – 2 hours

12. Transformative trends in oncology: New Frontiers in Treatment – Dr. István Peták

13. Recent Advances in Vaccine Development: Innovation, Efficacy, and Impact – Dr. János Szebeni, professor, Dr. Julianna Lisziewicz– 2 hours

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Other courses with overlapping topics (obligatory, optional, or elective courses) in interdisciplinary areas. To minimalize overlaps, topics should be coordinated. Code(s) of courses (to be provided):

Discovery of medicines

Requirements for attendance, options for making up missed sessions, and method of absence justification:

Full attendance is required. Completing additional e-learning materials are required to make up missed courses.

Assessment methods during semester (number, topics, and dates of midterms and reports, method of inclusion in the course grade, opportunities for make-up and improvement of marks):

(number, topics, and dates of midterms and reports, method of inclusion in the course grade, opportunities for make-up and improvement of marks)

MCQ completed at the end of Modul I with two make-up opportunities.

Number and type of individual assignments to be completed, submission deadlines:

January 26, 2026

Requirements for the successful completion of the course:

Written multiple choice test at the end of the semester, evaluation with the five mark scale (excellent=5, good=4, average=3, satisfactory=2, unsatifactory=1)

Examination requirements (list of examination topics, subject areas of tests, lists of mandatory parameters, figures, concepts and calculations, practical skills, optional topics for the project assignment recognized as an exam and the criteria for its completion and evaluation)

Topics from Modul I and II

Method and type of grading (Share of theoretical and practical examinations in the overall evaluation. Inclusion of the results in the end-of-term assessment. Possibilities of and conditions for offered grades.): (Share of theoretical and practical examinations in the overall evaluation, Inclusion of

the results in the end-of-term assessment, Possibilities of and conditions for offered grades)

Formulation of the grade:
88 to 100 points: excellent (5)
76-87,5 points: good (4)
63-75 points: average (3)
50-62 points: satisfactory (2)
Less than 50 points: unsatisfactory (1)

Signature of habilitated instructor (course coordinator) announcing the course:

Prof. Dr. Péter Ferdinandy
Head of Department

Signature of the director of the host institution:

Prof. Dr. Péter Ferdinandy
Head of Department

Date of submission:

8th August 2025

Semmelweis University, Faculty of Medicine

Pharmaceutical Innovation and Business Administration Master of Science

Name of the host institution (and any contributing institution):

Department of Pharmacology and Pharmacotherapy

Name of subject: Pharmaceutical Innovation Life Science Ecosystems – Evolution, Management Needs and Research Skills

in English: Pharmaceutical Innovation Life Science Ecosystems – Evolution, Management Needs and Research Skills

in German: not applicable

Credit value: 5

Semester: 2025/2026 1st Semester

in which the subject is taught according to the curriculum

Hours per semester	Lecture	Course work	Seminar
150		130	20

Hours per week	Lecture	Practical lesson	Seminar
Course blocks tailored to the students' employment obligations in person on 26-27th September, and online on Fridays and Saturdays in total 6 hours			

Type of course:

compulsory

Academic year:

2025/2026

Language of instruction (for optional and elective subjects):

English

Course code:

(in the case of a new course, to be completed by the Dean's Office, following approval

Course coordinator name:

Péter Ferdinandy
collaborator: András Fehérváry, MBA, MALD, DES (PhD Cand.)

Course coordinator location of work, telephone availability: Department of Pharmacology and Pharmacotherapy, 1089 Budapest, Nagyvárad tér 4. Tel: +36-1-2104416, e-mail: ferdinandy.peter@semmelweis.hu; fehervary.istvan@phd.semmelweis.hu

Course coordinator position: Head of Department, full professor

Course coordinator Date and number of habilitation: June 2 2001., 26/2001 Hab..

Objective of instruction and its place in the curriculum:

The course introduces students to the governance, design, and evolution of pharmaceutical innovation ecosystems. It connects theory, policy, and practical tools for analyzing national and regional biopharma innovation strategies. Students gain interdisciplinary insight into regulatory frameworks, innovation management, research translation, and international benchmarking in life sciences.

Method of instruction (lecture, group work, practical lesson, etc.):
Lecture, case-based learning, policy simulation, group work

Competencies acquired through completion of course:

Understand ecosystem governance frameworks

Analyze benchmarking indices (e.g., GII, UK LSCI, IMD)

Compare innovation ecosystems through real-world case studies

Apply policy tools and strategy models for ecosystem planning

Develop interdisciplinary research and leadership skills

Course outcome (names and codes of related subjects):
None

Prerequisites for course registration and completion: (CODE):
None

In the case of multi-semester courses, position on the possibility of and conditions for concurrent registration:

none

The number of students required to start the course (minimum, maximum), student selection method:

all students admitted to the MSc course

Detailed course syllabus (if the course can be divided into modules, please indicate):

(Theoretical and practical instruction must be broken down into hours (weeks), numbered separately; names of instructors and lecturers must be

listed, indicating guest lecturers/instructors. It cannot be attached separately! For guest lecturers, attachment of CV is required in all cases!)

In-person module: 14 hours

Day 1: Foundations and Evolution of Pharma Innovation Ecosystems

13:00 – Welcome & Orientation

13:30 – Session 1: Defining Innovation Ecosystems

14:00 – Session 2: Theoretical Frameworks (Porter, Mazzucato, Triple Helix)

14:30 – Session 3: Innovation Indices Deep Dive

15:15 – Session 4: Comparative Ecosystem Case Studies

17:00 – Wrap-up and Reflection

Day 2: Strategic Design and Management

09:00 – Session 5: Governance and Policy Levers

10:30 – Session 6: Designing Ecosystems

12:00 – Session 7: Applied Design Workshop

13:00 – Session 8: Management Skills

14:00 – Roundtable: Future Directions

15:00 – Wrap-up & Online Learning Brief

Online Module (Autumn): Translational governance, policy simulation, global value chains (6 hours)

Other courses with overlapping topics (obligatory, optional, or elective courses) in interdisciplinary areas. To minimalize overlaps, topics should be coordinated. Code(s) of courses (to be provided):

None

Requirements for attendance, options for making up missed sessions, and method of absence justification:

Mandatory full attendance for the in-person weekend sessions. One justified absence allowed.

Assessment methods during semester (number, topics, and dates of midterms and reports, method of inclusion in the course grade, opportunities for make-up and improvement of marks):

Group project (40%), written reflection on online modules (30%), participation (30%)

(number, topics, and dates of midterms and reports, method of inclusion in the course grade, opportunities for make-up and improvement of marks)

Number and type of individual assignments to be completed, submission deadlines:

1 group project; 1 written report (1,000 words)

Requirements for the successful completion of the course:

Completion of both group and individual assignments; attendance

Type of assessment:

Mid-term group project and written assignment (no exam)

Examination requirements (list of examination topics, subject areas of tests, lists of mandatory parameters, figures, concepts and calculations, practical skills, optional topics for the project assignment recognized as an exam and the criteria for its completion and evaluation)

Assessment based on applied understanding of ecosystem models, policy frameworks, and benchmark analysis

Method and type of grading (Share of theoretical and practical examinations in the overall evaluation. Inclusion of the results in the end-of-term assessment. Possibilities of and conditions for offered grades.): (Share of theoretical and practical examinations in the overall evaluation, Inclusion of the results in the end-of-term assessment, Possibilities of and conditions for offered grades)

Signature of habilitated instructor (course coordinator) announcing the course:

Prof. Dr. Péter Ferdinandy
Head of Department

Signature of the director of the host institution:

Prof. Dr. Péter Ferdinandy
Head of Department

Date of submission:

8th August 2025

Semmelweis University, Faculty of Medicine

Pharmaceutical Innovation and Business Administration Master of Science

Name of the host institution (and any contributing institution):

Department of Pharmacology and Pharmacotherapy hosting the MSc course announcing this specific subject in collaboration with the Richter Department

Name of subject: Preclinical Discovery of Medicines

in English: Preclinical Discovery of Medicines

in German: not applicable

Credit value: 5

Semester: 2025/2026 1st Semester

in which the subject is taught according to the curriculum

Hours per semester	Lecture	Course work	Seminar
150	28	122	-

Hours per week	Lecture	Practical lesson	Seminar
Course blocks tailored to the students' employment obligations on Fridays and Saturdays Course dates: 12th September 14.00-18.00 13rd September 9.00-13.00 19th September 14.00-18.00 20th September 9.00-13.00 18th October 9.00-13.00 25th October 9.00-13.00 8th November 9.00-13.00			

Type of course:

compulsory

Academic year:

2025/2026

Language of instruction (for optional and elective subjects):

English

Course code:

(in the case of a new course, to be completed by the Dean's Office, following approval

Course coordinator name: Balazs Lendvai MD PhD DSc

Course coordinator location of work, telephone availability: Semmelweis University Richter Department Budapest, 1085 Budapest, Üllői út 26. +36-20-240-9058

Course coordinator position: Head of Richter Department (Semmelweis University), Manager of division, Pharmacological and Drug Safety Research (Gedeon Richter Plc.),

Course coordinator Date and number of habilitation: -

Objective of instruction and its place in the curriculum:

The main objective is to provide an overall perspective of the R&D processes taken place in pharma industry including the major elements and specific knowledge of the area. In particular, there is a special focus on preclinical research where the discovery of next drug molecules happens and also involves the various aspects of drug developments and related modalities. It shows the details of various options of chemical starting points, the methods of finding new molecular targets, the screening of compound libraries, and the basis of pharmacokinetics and metabolism. The lectures allow deep insight to the fields of in vivo disease models, the current methodologies of translational research in pharma context, and actual challenges are also introduced for safety pharmacology the preclinical prediction is in focus. Moreover, the aspects of drug development are also discussed in relation to the discovery process. The lecturers are employees of Richter Gedeon and Richter Department of Semmelweis University, best experts in their specific fields, so that the specific knowledge is delivered from first hands. The success of these experts is highlighted by the approved medicines and ongoing clinical trials originated from this professional working group.

Method of instruction (lecture, group work, practical lesson, etc.):

lectures, group work

Competencies acquired through completion of course:

knowledge of basic information, timelines and practices of drug research

Course outcome (names and codes of related subjects):

-

Prerequisites for course registration and completion: (CODE):

no special prerequisite for the students admitted to the MSc Course

In the case of multi-semester courses, position on the possibility of and conditions for concurrent registration:

none

The number of students required to start the course (minimum, maximum), student selection method:

all students admitted to the MSc course

Detailed course syllabus (if the course can be divided into modules, please indicate):

(Theoretical and practical instruction must be broken down into hours (weeks), numbered separately; names of instructors and lecturers must be listed, indicating guest lecturers/instructors. It cannot be attached separately! For guest lecturers, attachment of CV is required in all cases!)

1. Trends in pharma industry: Role of the small molecule research and development - Balázs Lendvai MD PhD DSc - 2x45'
2. The flow of original drug research in pharma - Balázs Lendvai MD PhD DSc - 2x45'
3. Molecular drug targets: sources and determinants, Balázs Lendvai MD PhD DSc 2x45'
4. Success rate and attrition in pharma drug research- Balázs Lendvai MD PhD DSc -2x45'
5. Examples from the history of Drug Research: lessons to learn - András Boros MSc Phd - 2x45'
6. Mechanism of action of drugs in Central Nervous System -András Boros MSc Phd - 2x45'
7. New drug targets-András Boros MSc Phd - 2x45'
8. Cell and gene therapies: new waves in pharma drug research -András Boros MSc Phd - 2x45'
9. Discovery pharmacokinetics in the preclinical stage - Ottilia Balázs MSc PhD - 2x45
10. Medicinal chemistry approaches for drug screening - János Éles MSc PhD - 2x45'
11. Current efficacy screening practices in vitro - Tamás Kovács MSc PhD - 2x45'
12. Induced pluripotent stem cells and in vitro disease modelling in the pharma - Zsolt Némethy MSc PhD - 2x45'
13. Toxicokinetic and human clinical pharmacokinetic studies in the development - Attila Kónya MSc PhD - 2x45'
14. Bioanalytical development practice - Attila Kónya MSc PhD - 2x45'

Other courses with overlapping topics (obligatory, optional, or elective courses) in interdisciplinary areas. To minimalize overlaps, topics should be coordinated. Code(s) of courses (to be provided):

none

Requirements for attendance, options for making up missed sessions, and method of absence justification:

Full attendance is required. Completing additional e-learning materials are required to make up missed courses.

Assessment methods during semester (number, topics, and dates of midterms and reports, method of inclusion in the course grade, opportunities for make-up and improvement of marks):

(number, topics, and dates of midterms and reports, method of inclusion in the course grade, opportunities for make-up and improvement of marks)

online test at the end of the semester

Number and type of individual assignments to be completed, submission deadlines:

project work focused on a given topic, after the end of lectures

Requirements for the successful completion of the course:

project work approved + appropriate test results

Type of assessment:

score-based

Examination requirements (list of examination topics, subject areas of tests, lists of mandatory parameters, figures, concepts and calculations, practical skills, optional topics for the project assignment recognized as an exam and the criteria for its completion and evaluation)

project work submitted – test completed. Test includes questions regarding all topics of the subject.

Method and type of grading (Share of theoretical and practical examinations in the overall evaluation. Inclusion of the results in the end-of-term assessment. Possibilities of and conditions for offered grades.): (Share of theoretical and practical examinations in the overall evaluation, Inclusion of the results in the end-of-term assessment, Possibilities of and conditions for offered grades)

score-based evaluation of the test results. Assessment of the project work: whether it reached the required level.

Signature of habilitated instructor (course coordinator) announcing the course:

Signature of the director of the host institution:

Richter Department

Semmelweis University

Date of submission:

8th August 2025

2025.08.06.